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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,512	03/14/2002	Jacques Galipeau	2626-1-001	4833

23565 7590 02/09/2005

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EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,512	GALIPEAU, JACQUES	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-11 and 14-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13 and 18-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to paper filed 18 October 2004.

This action is on claims 13 and 18-23.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 13 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended the claims and the rejection is moot.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The burden of the written description requirement in this application for therapeutic nucleic acid sequences and nucleobase analogs has not been met.

The written description in this case only sets forth thymidine kinase (TK) and gancyclovir (GCV) as a combination that is therapeutic.

Claim Rejections - 35 USC § 102

Claim 13 was rejected under 35 U.S.C. 102(b) as being anticipated by Deliganis *et al.*

Applicant has amended the claim such that the rejection is withdrawn because the claim requires a bicistronic vector. Applicant's argument that the instant invention is the first cell free delivery method is not reflected in the claims as written.

Rejections Maintained

Claim Rejections - 35 USC § 112

Claims 13 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method using thymidine kinase (TK) and gancyclovir (GCV) as a combination that is therapeutic, does not reasonably provide enablement for all therapeutic nucleotide sequence and nucleobase analogs. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant invention is not enabled for the broadly claimed method of treating tumors.

Thus, the specification provides insufficient guidance with regard to theses issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed method of treatment with a reasonable expectation of success. Moreover, the nature of the invention and the state of prior art have not provided any reasonable expectation of success in the treatment of the lung cancer. For the above reasons, it appears that undue experimentation would be required to practice the claimed inventions with a reasonable expectation of success.

Applicant argues that they have amended the claims to recite a specific therapeutic combination and thus are enabled.

Applicant's argument has been fully considered and not found persuasive.

Applicant has not addressed the issues set forth in the rejection concerning the unpredictability of the art and the lack of specific guidance in the specification to practice the method claimed.

The rejection is maintained.

Claim Rejections - 35 USC § 102

Claims 13 and 18-20, 22, and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Nalbantoglu *et al.* (Neurology 1999, from IDS).

Applicant argues that the rejection under 102(b) is improper and that the instant application has an earliest USA filing date of 23 April 1999 (provisional application).

Applicant's arguments have been fully considered and not found persuasive.

The rejection is based on 102(a) as indicated in the previous action.

The date of the abstract in question is not December 1999 as argued by Applicant. The date on the reference in manuscript from the European Search Report is 12 April 1999 (12-4-1999)(European convention of day-month-year). This is further supported by the received date from the copy in the USPTO Biotech Library of 16 April 1999 (copy can be supplied if needed). It is also noted that the copy of the journal page with the reference clearly states "April" next to the year, volume and title.

The new claims recite limitations are disclosed in the cited art or are well known (CMV promoter for expression in mammalian cells).

The rejection is maintained.

New Rejections Necessitated By Amendment

Claims 13 and 18-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 now provides a list of parts but it is

not clear how they form the vector and they do not resemble the vector of Figure 1 or vectors described in the specification.

In claim 21 it is not clear how the fusion is expressed. Is the fusion protein expressed in addition to or in place of one of the first or second expressed nucleic acids of claim 13?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deliganis *et al.* and Loimas *et al.* (Herpes Simplex Virus Thymidine Kinase-Green Fluorescent Protein Fusion Gene: New Tool for Gene Transfer Studies and Gene Therapy 1998 Bio Techniques Vol 24 No 4, pages 614-618).

The invention is drawn to a method of inhibiting tumor growth in a mammal comprising administering a viral vector with a TK gene and administering gancyclovir.

Deliganis *et al.* as discussed in the 102(b) rejection in the previous action teaches a method of treating and inhibiting by delivering TK by way of a viral vector and administering gancyclovir.

Deliganis *et al.* does not teach a TK-GFP fusion.

Loimas *et al.* teach a TK-GFP fusion protein (page 614).

One of ordinary skill in the art at the time of invention would have been been motivated to use the fusion protein of Loimas *et al.* because the TK part has been shown to function as a suicide gene with gancyclovir (Figure 4) and the GFP marker is expressed in equal amounts to allow for specific quantitation of suicide gene for gene therapy and this overcomes a problem in the prior art of knowing how much therapeutic gene was being delivered (page 614, column 2, middle).

It is also noted that in Applicant's arguments concerning Deliganis *et al.* in paper this action is in response to, Applicant argues "cell free" delivery of vector. Applicant has amended the claim to be bicistronic but has not excluded cells or required delivery of viral particles comprising the viral vector.

Thus, it would be prima facie obvious to modify the method of Deliganis *et al.* with the fusion protein of Loimas *et al.* to carry out the method with the added benefit of being able to determine transfer efficiency.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Myron G. Hill
Patent Examiner
February 6, 2005

ALI R. SALIMI
PRIMARY EXAMINER